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10/525,878	09/27/2005	Kenji Yasuda	2005-0296A	4129

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EXAMINER	
HOBBS, MICHAEL L	

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1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,878	YASUDA, KENJI	
	Examiner	Art Unit	
	MICHAEL HOBBS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11 and 13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11 and 13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 12/01/2008 has been considered and entered for the record. Claims 6-11 and 13-25 are pending further examination upon the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. It would be unclear to one of ordinary skill in the art as to whether each electrode in the pattern is isolated from one another or if the entire pattern is isolated within a cell culture chamber from other chambers containing an equivalent electrode pattern. The Examiner is interpreting this limitation to mean that the individual electrodes within an electrode pattern are isolated from one another by a wall or separate well.

5. Appropriate corrective action is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 6, 7, 9, 11, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Klemic et al. (US 6,699,697 B2) in view of Yasuda et al. (US 7,092,154 B1) (will be referred to as Yasuda).

The applied reference, Yasuda, has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing

that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

9. With regards to isolating each electrode, Klemic discloses a planar patch clamp electrode that includes multiple electrodes or electrode patterns within dish well (Fig. 4) where each electrode has its own well or wall where the well holds one cell (Fig. 1a). The well or wall is made of PDMS, but other materials can be used to make the wells based on the size of the electrodes and the electrode array. The electrodes are being interpreted as corresponding to the isolated regions or electrodes of the pattern. However, Klemic is silent regarding an optically transparent membrane over the regions.

10. Yasuda discloses an apparatus for microscopic observation of long-term cultures that includes the cells being formed onto a substrate covered with a semi-permeable membrane. For claim 6, Yasuda discloses that the membrane used to cover the cells is an optically transparent membrane (col. 2 lines 57-58) and the membrane is coarse enough to prevent cells form passing through the membrane (col. 2 lines 58-59). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Yasuda in order to retain the cells within the wells of Klemic. The suggestion for doing so at the time would have been in order to prevent the cells from coming out of the hole or well (col. 2 lines 59-61).

11. For claim 7, as discussed above for claim 6, Klemic has electrodes that are fully capable of measuring the electrophysiological properties of a sample and stimulating nerve cells (see also MPEP § 2115).

12. With regards to claims 9, 11 and 16, Klemic discloses an electrode pattern that includes at least three electrodes that are fully capable of carrying out measurements independently (Fig. 4).

13. With regards to claim 13, Klemic discloses mounting the entire assembly onto a microscope stage or holder where the silver wire connecting the electrodes was connected to the head-stage input of an Axolpatch 200B amplifier (col. 23 lines 48-53). In this case, an oocyte was dropped into the chamber and the iconic currents were recorded and sense the assembly was mounted onto a microscope stage, it is an intrinsic step of the system that optical observations of the cell would occur simultaneously with the electrical measurements (col. 23 lines 58-62).

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klemic et al. (US 6,699,697 B2) in view of Yasuda et al. (US 7,092,154 B1) (will be referred to as Yasuda) and in further view of Varalli et al. (US 2001/0041830 A1) (will be referred to as Varalli).

15. Both Klemic and Yasuda are silent regarding the amplifier and computer being optically connected.

16. Varalli discloses an apparatus for measuring the content of glucose, lactate and other metabolites in biological fluids. Varalli also includes a measurement instrument that is connected to a patient and that transmits the data from the measuring device back to a computer. For claim 14, Varalli discloses that the connection between the measurement instrument and an external computer is an IR optical transmission system

([0037]). Other optical transmission systems that are known and used, for example, for connections between computers and peripheral units (for example, between the HP-42S and a printer) include protocols such as IRLAP (from the Infrared Data Association) and the Infrared Physical Layer Link which is used on some HP components ([0038]). Therefore, it would be obvious to one of ordinary skill in the art to employ the optical connections suggested by Varalli in order to connect the electrode array of Klemic and Yasuda with a computer. The suggestion for doing so at the time would have been in order to guarantee the total electrical isolation of the electrical circuits for the measurement system ([0037]).

17. Claims 6, 7, 9, 11, 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klemic et al. (US 6,699,697 B2) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni).

18. With regards to isolating each electrode, Klemic discloses a planar patch clamp electrode that includes multiple electrodes or electrode patterns within dish well (Fig. 4) where each electrode has its own well or wall where the well holds one cell (Fig. 1a). The well or wall is made of PDMS, but other materials can be used to make the wells based on the size of the electrodes and the electrode array. The electrodes are being interpreted as corresponding to the isolated regions or electrodes of the pattern. However, Klemic is silent regarding an optically transparent membrane over the regions

19. Hänni discloses a device for organic cell culture for testing the electrophysiological activity of nerve cells. For claim 6, Hänni discloses that a

transparent porous membrane (membrane 16) is placed on the support structure (support 11) in order to cover an opening (opening 15; col. 3 lines 9-11). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Hänni in order to retain the cells within the wells of Klemic. The suggestion for doing so at the time would have been in order to provide a cover for the opening (col. 3 lines 11-12).

20. For claim 7, as discussed above for claim 6, Klemic has electrodes that are fully capable of measuring the electrophysiological properties of a sample and stimulating nerve cells (see also MPEP § 2115).

21. With regards to claims 9, 11 and 16, Klemic discloses an electrode pattern that includes at least three electrodes that are fully capable of carrying out measurements independently (Fig. 4).

22. With regards to claim 13, Klemic discloses mounting the entire assembly onto a microscope stage or holder where the silver wire connecting the electrodes was connected to the head-stage input of an Axolpatch 200B amplifier (col. 23 lines 48-53). In this case, an oocyte was dropped into the chamber and the iconic currents were recorded and sense the assembly was mounted onto a microscope stage, it is an intrinsic step of the system that optical observations of the cell would occur simultaneously with the electrical measurements (col. 23 lines 58-62).

23. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) in views of Klemic et al.

(US 6,699,697 B2) and Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) and in further view of Varalli et al. (US 2001/0041830 A1) (will be referred to as Varalli).

24. Both Sugihara and Hänni are silent regarding the amplifier and computer being optically connected.

25. Varalli discloses an apparatus for measuring the content of glucose, lactate and other metabolites in biological fluids. Varalli also includes a measurement instrument that is connected to a patient and that transmits the data from the measuring device back to a computer. For claim 14, Varalli discloses that the connection between the measurement instrument and an external computer is an IR optical transmission system ([0037]). Other optical transmission systems that are known and used, for example, for connections between computers and peripheral units (for example, between the HP-42S and a printer) include protocols such as IRLAP (from the Infrared Data Association) and the Infrared Physical Layer Link which is used on some HP components ([0038]). Therefore, it would be obvious to one of ordinary skill in the art to employ the optical connections suggested by Varalli in order to connect the electrode array of Sugihara, Klemic and Hänni with a computer. The suggestion for doing so at the time would have been in order to guarantee the total electrical isolation of the electrical circuits for the measurement system ([0037]).

26. Claims 8, 10, 15, 17 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Klemic et al. (US 6,699,697 B2) in view of Hänni et al. (US

6,689,594 B1) (will be referred to as Hänni) and in further view of Sugihara et al. (WO 99/34202) (will be referred to as Sugihara).

27. With regards to claims 8 and 15, Klemic and Hänni are silent regarding electrodes made of an optically transparent material.

28. Sugihara discloses a cell potential measuring electrode used to measure the electrophysiological activities of a sample that includes a plural micro-electrodes mounted on an insulating substrate (page 3 lines 8-10) that are placed in plural positions enclosed by a wall (page 3 lines 14-16). Furthermore, the micro-electrodes and reference electrodes are formed of layers of nickel plating, gold plating and platinum black on an indium-tin oxide (ITO) film (page 4 lines 20-21). While not specifying that the electrodes are made of ITO (which is transparent), it is well within the skills of one of ordinary skill in the art to make electrodes out of ITO in order to have transparent electrodes. Furthermore, the use of ITO to make electrodes is known within the art (refer to US 5,810,725). Therefore, it would have been obvious for one of ordinary skill in the art to try the ITO electrodes as suggested by Sugihara within Klemic and Hänni in order to obtain the predictable result of having an optically transparent electrode to supply current to the cells.

29. With regards to claims 17 and 18, Klemic discloses an electrode pattern that includes at least three electrodes that are fully capable of carrying out measurements independently (Fig. 4).

30. For claims 10 and 19-25, Klemic and Hänni are silent about the walls being made of a photo-curable resin.

31. With regards to claims 10 and 19-25, Sugihara further discloses that the electrode sites or compartments are formed by applying the ITO film to a glass substrate and the conductive pattern is formed by photo-resist and etching (page 10 lines 15-16). The insulating film is formed by a negative photosensitive polyimide film or photo-curable resin (page 10 lines 16-17). Furthermore, Sugihara demonstrates that using a photo-curable material to form a culture chamber for cells was known at the time of the instant application. Therefore, following rationale C of *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396, it would have been obvious to one of ordinary skill in the art to employ the photo-curable resin suggested by Sugihara within the culture chamber of Klemic and Hänni in order to construct the well walls with predictable results.

Response to Arguments

32. Applicant's arguments with respect to claims 6-11 and 13-25 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection is made in view of Klemic which discloses a multi-well plate with electrode patterns isolated from one another where the electrodes within the patterns are capable of performing electro-physiological measurements on a cell.

33. Applicant's remarks on page 5 section 3 paragraph 2 that the reference US 2001/0041830 A1 was not cited on the Notices of References cited has been noted and the patent number has been listed as a reference cited in this action.

Conclusion

34. Claims 6-11 and 13-25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M. H./
Examiner, Art Unit 1797